K041757

DEC 23 2004

SECTION V: 510(K) SUMMARY:

510(k) Summary

FemSpec Disposable Vaginal Speculum

Date Prepared:

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

FemSpec
220 Halleck Street, Suite 120
San Francisco, CA 94129-0450

B. Company Contact

Gerald Jay Sanders, CEO

C. Device Name

Trade Name:	FemSpec Disposable Vaginal Speculum
Common Name:	Disposable Vaginal Speculum
Classification Name:	Non-metal Vaginal Speculum
Classification:	Class II per 21 CFR 884.4530

D. Predicate Devices

K012535 - Doctors Research Group SoftSpec Vaginal Speculum

E. Description of Device

The FemSpec disposable vaginal speculum consists of a soft plastic inflatable bladder, which once inserted into the vagina is inflated to uniformly press the vaginal wall open. Once inflated the bladder generates an annular space for diagnostic procedures of the cervix.

D. Intended Use

The FemSpec disposable vaginal speculum is indicated for diagnostic procedures of the cervix.

E. Comparison of Technological Characteristics

The basic technology, design, mode of operation, materials of construction and intended use of the FemSpec™ disposable vaginal speculum is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

Mr. Gerald Jay Sanders
CEO
FemSpec L.L.C.
220 Halleck Street, Suite 120B
P.O. Box 29450
SAN FRANCISCO CA 94129

Re: K041757
Trade/Device Name: FemSpec™ Disposable Vaginal Speculum
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 HIB
Dated: October 19, 2004
Received: October 20, 2004

Dear Mr. Sanders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: FemSpec™ Disposable Vaginal Speculum

Indications for Use:

The FemSpec™ disposable vaginal speculum is indicated for diagnostic procedures of the cervix.

Prescription Use: X
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use:_____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyons

Abdominal,

K041757